

Application No. 10/521,823
Response dated July 12, 2010
Reply to Office Action mailed on May 11, 2010
Docket No. 1199-13 PCT/US
Page 2

REMARKS/ARGUMENTS

Reconsideration is respectfully requested in view of the remarks presented herein.

Status of the Claims

Claims 1-28 are pending in the application. Claims 11-15, 18, and 21-28 have been previously withdrawn from consideration by the Examiner as drawn to non-elected subject matter.

Response to the Rejection under 35 U.S.C. §103(a) in view of Cremer

Claims 1-7, 16, 17, 19 and 20 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over U.S. Patent No. 6,655,112 to Cremer et al. (hereinafter “Cremer”). Although the Examiner has acknowledged that “Cremer’s dosage units are individually sealed and compartmentalized, whereby the perforations occur in the packaging and not the film,” the Examiner has stated that “there is nothing in the instant claims that would exclude the individually sealed or packaged dosage units disclosed by Cremer.” (Office Action, page 5). In particular, the Examiner has alleged that “the instant claim language does not exclude the ‘single’ dosage units of Cremer.” (*Id.*). Applicants respectfully traverse the rejection and request reconsideration for the reasons set forth below.

Claim 1 requires a film which includes dosage units which are releasably joined by one or more weakened sections. Accordingly, the film of claim 1 itself includes more than one dosage unit and also includes weakened sections. In particular, the weakened sections releasably join the dosage units and permit the dosage units to be detached from the film.

In contrast to the film of claim 1, the film of Cremer does not include weakened sections which releasably join dosage units. Rather, as acknowledged by the Examiner, the perforations

Application No. 10/521,823
Response dated July 12, 2010
Reply to Office Action mailed on May 11, 2010
Docket No. 1199-13 PCT/US
Page 3

of Cremer are within the packaging material. In particular, Cremer specifically states the following:

It was found that a primary packaging unit which satisfactorily fulfils [sic] the objects of the present invention must also have an additional characteristic: a perforation between the compartments in which the individual dosage units are situated, whereby said perforation must be such that it is possible, for the extraction of a single dosage unit, to first separate the compartment containing this dosage unit from the primary packaging unit

(Col. 4, lines 21-28, of Cremer).

Accordingly, Cremer manufactures individual dosage units of film and packages them into separate packaging units in keeping with Cremer et al.'s purpose of providing for "the targeted removal of a single dosage unit by pressing it through the primary packaging unit." (Col. 4, lines 15-16, of Cremer). Indeed, Cremer's manufacturing process is designed "in such a way that the single dosage units 5 are sealed into compartments 8 and are completely enclosed by sealed seams or sealed areas 9." (Col. 7, lines 14-16, of Cremer et al.). Thus, Cremer fails to disclose film including dosage units releasably joined by one or more weakened sections which permit the dosage units to be detached from the film, as required by claim 1.

Significantly, under *KSR International v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385 (2007), a rationale must be provided to support an obviousness rejection. (See MPEP §2141.III.). MPEP §2141.III sets forth seven permissible rationales under *KSR*, and MPEP §§2143(A)-(G) set forth the showing required under each of those rationales. The Examiner, however, has not pointed to any particular rationale under MPEP §2141.III, let alone made a showing of obviousness under any of the rationales set forth in MPEP §2141.III.

Rather, the Examiner has simply alleged that "Cremer meets the edible film as claimed based upon the same features and elements." (Office Action, page 3). However, in view of the

Application No. 10/521,823
Response dated July 12, 2010
Reply to Office Action mailed on May 11, 2010
Docket No. 1199-13 PCT/US
Page 4

foregoing discussion, Applicants respectfully submit that it is not the case that Cremer meets the edible film based upon the same features and elements of the film recited in claim 1.

Applicants respectfully submit that no rationale under MPEP §2141.III supports a *prima facie* case of obviousness in view of Cremer. Moreover, any modification of Cremer's film to anything other than single dosage units would render the film of Cremer unsuitable for its intended purpose of being separately packaged and also would directly contravene the principle of operation of Cremer's manufacturing process, which specifically allows for the packaging of single dosage units into separately sealed compartments. *See* MPEP §2143.01.V (internal citations omitted) (indicating that if a "proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification"); *see also* MPEP 2143.02.VI (internal citation omitted) (indicating that if a proposed modification would change the principle of operation of the prior art invention being modified, then the teaching of the reference is not sufficient to render the claims *prima facie* obvious).

Applicants respectfully submit that it appears that it is only through hindsight reconstruction using Applicants' disclosure as a blueprint that the Examiner attempts to reach the present invention based upon the disclosure of Cremer. Hindsight reconstruction using only Applicants' disclosure to arrive at the present invention is, however, strictly prohibited. *See* M.P.E.P. § 2145.X.A.; *see also* *KSR International Co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1397 (2007) (internal citations omitted) ("[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.").

Claim 1 is thus not obvious in view of Cremer. Claims 2-7, 16, 17, 19, and 20 all depend either directly or indirectly from claim 1. Accordingly, claims 2-7, 16, 17, 19, and 20 are not

obvious in view of Cremer for the same reasons discussed above with respect to claim 1. Indeed, there is no disclosure or suggestion in Cremer of the subject matter of claims 2-7, 16, 17, 19, and 20.

In view of the foregoing, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a) with regard to claims 1-7, 16, 17, 19, and 20 in view of Cremer.

Response to the Rejection under 35 U.S.C. §103(a) in view of Chen

Claims 1-10, 16, 17, 19 and 20 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over WO 00/42992 to Chen et al. (hereinafter “Chen”). In the Office Action, the Examiner has alleged that “the prior art vividly teaches a product as claimed herein, having the structural elements and features (i.e., perforated dosage units) as presently claimed.” (Office Action, page 6). Moreover, the Examiner has alleged that “[t]he limitation of ‘releasably joined....which permit the dosage units to be detached from the film’ denotes a future-intended use limitation which does not accord patentable weight to the claims.” (*Id.*). Applicants respectfully traverse the rejection and request reconsideration for the reasons set forth below.

Claim 1 requires a film which includes dosage units which are releasably joined by one or more weakened sections. Accordingly, the film of claim 1 includes more than one dosage unit and also includes weakened sections. In particular, the weakened sections releasably join the dosage units and permit the dosage units to be detached from the film.

Contrary to the contention of the Examiner, the phrase “releasably joined...which permit said dosage units to be detached from said film” is not “a future-intended use limitation.” Rather, the feature of the dosage units being releasably joined by one or more weakened sections and the feature of the weakened sections permitting the dosage units to be detached from the film are characteristics of the film.

Application No. 10/521,823
Response dated July 12, 2010
Reply to Office Action mailed on May 11, 2010
Docket No. 1199-13 PCT/US
Page 6

In support of the rejection, the Examiner has cited page 6, lines 4-8 of Chen, which refers to a “perforated film strip” (19), as shown in Figure 3. However, one of ordinary skill in the art would appreciate that the “perforated film strip 19” shown in Figure 3 of Chen is nothing more than a strip of film which has been cut into single dose film units. Indeed, there is no disclosure or suggestion in Chen of dosage units which are releasably joined by one or more weakened sections, as required by claim 1. Thus, contrary to the contention of the Examiner, Chen does not vividly teach a product as claimed.

Significantly, under *KSR International v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385 (2007), a rationale must be provided to support an obviousness rejection. (See MPEP §2141.III.). MPEP §2141.III sets forth seven permissible rationales under *KSR*, and MPEP §§2143(A)-(G) set forth the showing required under each of those rationales. The Examiner, however, has not pointed to any particular rationale under MPEP §2141.III, let alone made a showing of obviousness under any of the rationales articulated in MPEP §2141.III.

Rather, the Examiner has simply alleged that “Chen meets the edible film as claimed based upon the same features and elements.” (Office Action, page 3). However, in view of the foregoing discussion, Applicants respectfully submit that it is not the case that Chen meets the edible film based upon the same features and elements of the film recited in claim 1.

Applicants respectfully submit that no rationale under MPEP §2141.III supports a *prima facie* case of obviousness in view of Chen. Furthermore, Applicants respectfully submit that the fact that Chen is directed to distinct problems is pertinent and evidences that Chen, unlike the present invention, has nothing to do with providing film which has weakened sections which permit for ease of administration of a single dosage unit.

Application No. 10/521,823

Response dated July 12, 2010

Reply to Office Action mailed on May 11, 2010

Docket No. 1199-13 PCT/US

Page 7

Moreover, Applicants respectfully note that the Examiner has provided no reason as to why one of ordinary skill in the art would be motivated to modify the Chen reference to arrive at an oral dosage delivery vehicle which includes an edible film as recited in claim 1, let alone articulated a “sound basis for believing that the products of the applicant and the prior art are the same.” (Office Action, page 6). As such, Applicants respectfully submit that the Examiner’s comments on page 6 of the Office Action are unsubstantiated and improperly applied.

Applicants respectfully submit that it appears that it is only through hindsight reconstruction using Applicants’ disclosure as a blueprint that the Examiner attempts to reach the present invention based on the disclosure of Chen. Hindsight reconstruction using only Applicants’ disclosure to arrive at the present invention is, however, strictly prohibited. *See M.P.E.P. § 2145.X.A.; see also KSR International Co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1397 (2007) (internal citations omitted) (“[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.”).

Claim 1 is thus not obvious in view of Chen. Claims 2-10, 16, 17, 19, and 20 all depend either directly or indirectly from claim 1. Accordingly, claims 2-10, 16, 17, 19, and 20 are not obvious in view of Chen for the same reasons discussed above with respect to claim 1. Indeed, there is no disclosure or suggestion in Chen of the subject matter of claims 2-10, 16, 17, 19, and 20.

In view of the foregoing, Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. §103(a) with regard to claims 1-10, 16, 17, 19, and 20 in view of Chen.

Application No. 10/521,823
Response dated July 12, 2010
Reply to Office Action mailed on May 11, 2010
Docket No. 1199-13 PCT/US
Page 8

Concluding Remarks

This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned at the telephone number given below.

No fees are deemed due with this submission. However, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this submission or any future submission pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



Andrea M. Wilkovich
Registration No.: 53,773

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700